IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

HEIDI COOK and STEVEN COOK, Plaintiffs,	§	
vs.	§	CASE #: 3:12-cv-6292
ABBOTT LABORATORIES, and ABBVIE, INC., Defendants.	§	JURY TRIAL DEMANDED

COMPLAINT

Plaintiffs HEIDI COOK and STEVEN COOK, by and through their attorneys, PIERSON LEGAL SERVICES and PERDUE KIDD & VICKERY file this suit against Defendants ABBOTT LABORATORIES and ABBVIE, INC.[1], and for their causes of action against Defendants state and allege as follows:

Nature of the Case

1. This is a personal injury, products liability case. On April 17, 2008, Heidi Cook received Abbott's blockbuster arthritis drug "Humira" from her dermatologist in South Charleston, West Virginia. On November 4, 2011, as a result of taking this drug, she was hospitalized and treated for *histoplasmosis*, a life-threatening fungal infection.

2. Prior to Heidi being prescribed Humira, Abbott was acutely aware of the fact that by depressing the immune system, Humira would place patients like Heidi at a substantial risk for developing histoplasmosis. It was also aware of the need to call attention to the fact that some

[1] In October 2011, Abbott announced that in 2012 it would be reorganized into two distinct, publically traded corporations, Abbott and AbbVie. AbbVie would be a new research-based pharmaceutical company, while Abbott would primarily medical products and nutrition. Humira is/was to be assigned to AbbVie. While AbbVie has been launched, it is unclear at this point in time where Humira liabilities will be assigned. Thus, out of an abundance of caution, both companies are included as Defendants in this case. Upon Abbott or AbbVie's counsel informing the undersigned as to the true and correct party, the appropriate nonsuit will be filed.

individuals, by virtue of where they resided, were at significantly increased risk for developing this disease while taking Humira. By failing to timely implement and disseminate appropriate warnings pertaining to histoplasmosis to patients and doctors alike, Abbott failed to provide legally adequate warnings and instructions as required by law.

Parties

3. Plaintiffs Heidi and Steven Cook are husband and wife. They currently reside in Georgetown, Kentucky. However, they resided in Hurricane, West Virginia until July 2010.

4. Defendant Abbott Laboratories is an Illinois corporation organized and existing under the laws of Illinois, having its principal place of business located at 100 Abbott Park Road, Abbott Park, Illinois 60064. Abbott may be served with process by serving its registered agent, Laura J. Schumacher, 100 Abbott Park Rd., Abbott Park, Illinois 60064. Presumably its counsel will accept service as it has done in other Humira personal injury cases involving the undersigned counsel.

5. Defendant AbbVie, Inc., is a Delaware Corporation and wholly owned subsidiary of Abbott. It has its principle place of business at, and is headquartered in, Abbott Park, Illinois. AbbVie may be served with process by serving its registered agent, C. T. Corporation System, 208 S. LaSalle St., Suite 814, Chicago, Illinois, 60604. Presumably its counsel will accept service as it has done in several other Humira personal injury cases involving the undersigned counsel.

Jurisdiction and Venue

6. Abbott Laboratories is an Illinois corporation, headquartered in Abbott Park, Illinois. AbbVie, Inc. is a Delaware Corporation headquartered in Abbott Park, Illinois. Heidi and Steven Cook were residents of West Virginia prior to moving to Kentucky. The amount of damages exceeds $75,000, exclusive of interest and costs. Thus, as to both diversity and the amount in controversy, jurisdiction is proper under 28 U.S.C. § 1332.

7. It is specifically alleged that any wrongful conduct described herein by Abbott is imputed to AbbVie by virtue of any assignment of liabilities between the two companies during separation.

8. As the Court will see, the decision to prescribe Humira and actual use of the medication by Abbott happened in West Virginia. Additionally, Abbott's contact with Heidi and her prescribing physicians occurred in West Virginia. As a result, a substantial part of the events or omissions giving rise to this claim occurred in this district. Thereby, venue is appropriate in this forum under 28 U.S.C. § 1391.

Humira and the other "Tumor Necrosis Factor" Blockers

9. "Tumor Necrosis Factor" ["TNF"] is a naturally occurring substance in the human body. TNF is related to the workings of the body's immune system. There is a class of biologic drugs known as TNF-alpha blockers. The first two on the US market were Remicade and Enbrel. The third was Humira which was initially "launched" in December 2002 and has since become a multi-billion dollar, company-changing drug for Abbott. Humira is now the No. 1 selling drug in the world with sales last year of more than $8 *billion* dollars.

10. Although there are certainly some differences, generally speaking, the TNF blocker class of "biologic" drugs has the same presumed mode of action and the same general safety profile. Indeed, in its regulatory filings, and in its competitive and promotional activities, Abbott has specifically tried to capitalize on this by suggesting that Humira's effects in human beings are very similar to its two closest competitors, Enbrel and Remicade.

11. Because of their mode of action in the human body, there is a "biologically plausible" explanation for the causal association between Humira, and the other TNF-alpha blockers, and serious infection like histoplasmosis. Abbott's company witnesses have conceded as much in

depositions in the *Jones*[2] case pending in Memphis, Tennessee. This mode of action speaks to the inherent defect found in Humira that is not seen in alternative forms of treatment for psoriasis, the indication for which Heidi Cook was prescribed Humira.

Mass Marketing of a Blockbuster Medication

12. Humira, the generic name of which is "ADALIMUMAB,"[3] was not developed by Abbott Laboratories. Rather, the compound which began with the research code D2E7 was owned by a company called Knoll Pharmaceuticals. Abbott acquired the rights to this drug in March of 2001 when it purchased Knoll. Amazingly, it then managed to "fast track" the Biologics Licensing Application ["BLA"] for Humira and received FDA approval to market the drug in the record time of five months. Abbott launched Humira[4] worldwide in December 2002 to treat rheumatoid arthritis ["RA"]. Subsequently, it "launched" five other "indications" for this drug, including psoriasis, for which Heidi Cook was prescribed Humira.

13. Even though two other major biologic TNF blockers, *i.e.,* Enbrel and Remicade, had already been approved for RA, Abbott expected Humira to be a "blockbuster" drug for the company.

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[2] *Freddie Jones, et al. v. Abbott Laboratories*, (W.D. Tenn.)[2:07-cv-02120-SHM].

[3] Generic drug names are interesting. The first three letters, ADA, were selected by Abbott. The "LIM" means that it is an inflammation mediator, the "U" signifies that it was derived from human cells, and the "MAB" stands for a monoclonal antibody.

[4] As Stanford business researchers have noted, "The HUMIRA launch was global in scope, and Abbott Laboratories considered global coordination to be a critical success factor for bringing a blockbuster drug to market." Exhibit A, Stanford Graduate School of Business, ABBOTT LABORATORIES AND HUMIRA: LAUNCHING A BLOCKBUSTER DRUG, Case O1T-44 at p.2n.4. Condensed (6/25/2005)(written in cooperation with Abbott personnel)["ABBOTT BLOCKBUSTER"].

A "blockbuster" drug is commonly defined either (a) as a drug that generates more than $1 billion in annual sales, or (b) "at its peak sales level, typically account for 20%-30% of that company's total sales. . . . Blockbusters are, therefore, often products that define a company."[5]

14. By either of these measures, Humira has been a "blockbuster" for Abbott. Humira was launched in the United States at the beginning of 2003 and reached sales of approximately $246 million in its first year alone. By 2005, sales had reached $1.4 billion. Since that time, sales revenues have continued to grow. The 2009 worldwide sales were approximately $5.5 billion. By 2010, they had increased to approximately $6.5 billion. In 2011, they were more than $8 billion. The drug has become so large and financially lucrative that it has fostered a split of Abbott into two different publically traded companies.

15. Abbott achieved this stunning financial success by clever and aggressive marketing, focusing not only on the doctors who prescribe the medication but also on patients. From the start, according to one of its top marketing executives, "our overriding goal in going to market was to be exquisitely patient-friendly and doctor-supportive."[6]

"Patient Friendly"

16. From the start, Abbott has also undertaken significant efforts to "educate" patients about their disease states, thereby to empower them to "self-diagnose" and then, of course, to "ask for" Humira. They have done so by focusing patient attention on their drug through extensive marketing in the public domain. Abbott marketers know that in the vast majority of circumstances that a patient comes in to a medical office and "asks her doctor" about a medication she will receive

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[5] ABBOTT BLOCKBUSTER, *supra*, quoting *The Blockbuster Drug Outlook*, Reuter's Business Insight, *Datamonitor*, April 2001.

[6] A BBOTT BLOCKBUSTER, *supra* at p. 13.

a prescription for that medication. They also know that a strong, high-profile marketing presence via direct-to-consumer ["DTC"] advertising gives patients a sense of comfort and confidence in using Abbott drugs. This pervasive presence helps shape and influence a patient's decision making when it comes to Humira. Abbott's Humira promotional activities *vis-à-vis* patients themselves involved significant DTC advertising, DTC patient counseling,[7] and internet website promotion.

17. Abbott's DTC promotion of Humira illustrates the power of the well-known aphorism that a "picture is worth a thousand words." Communication specialists, including Abbott's marketing and advertising people, know that about 70% of the message that any audience receives comes from the *visual* images that they see. Abbott's DTC advertising sends consistent audio and visual messages about the *benefits*, but **inconsistent** messages about the risks of Humira.

18. Obviously, the inherent goal of this "patient friendly" advertising is not only to persuade patients to "ask for" Humira by name, but also to encourage and persuade patients to take Humira in the first instance. Unfortunately, they do so by discounting the risks and emphasizing the benefits that are touted by the prescriber. It is appalling and unjust that in most instances Abbott can employ such aggressive and targeted marketing efforts to consumers and yet still seek to hide behind the shortcomings of the very "learned intermediaries" (doctors) that it typically pays in order to avoid liability to citizens like Heidi Cook who have suffered legitimate, permanently life-altering, Humira-induced injuries.

19. Fortunately, in West Virginia, Abbott cannot hide behind the "learned intermediary"doctrine. On June 27, 2007, the West Virginia Supreme Court found this doctrine to be "outmoded and unpersuasive" and declined to adopt it as the law in this state. *State ex rel.*

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[7] Abbott has long employed 1-800-4HUMIRA as a nursing hotline for Humira patients. When a patient calls this number, they receive medical advice from an Abbott employed nurse.

Johnson & Johnson Corp. v. Karl, 220 W. Va. 463, 470, 647 S.E.2d 899, 906 (2007). Importantly, the Court noted that the logical underpinnings of the doctrine have been decimated by current pharmaceutical marketing practices, including both "direct-to-consumer" advertising and internet promotion of pharmaceutical products. *Id.* at 906-912. In other words, the exact activities that Abbott has engaged in to make its drug the No. 1 selling drug in the world.

20. Significantly, Heidi saw these types of Abbott advertisements ["ads"] both before she started Humira and while she was taking the drug. They assured her of the difference this drug would make in her life and of its appropriateness and safety. They not only influenced her decision to take the medication in the first instance but they also affected her decision to stay on the drug. She relied upon their accuracy with respect to both the efficaciousness of the drug, its appropriateness for patients like her, and its safety. These ads instilled in her the belief that the drug was revolutionary and gave her comfort and confidence that it was a safe, effective drug made by a reputable pharmaceutical company that stood behind its products.

21. Further, nothing in the ads viewed by Heidi communicated to her that starting or staying on Humira would place a patient at increased risk for histoplasmosis. Moreover, nothing told her that patients like herself were at additional increased risk because they lived in the Ohio River Valley, where histoplasmosis is endemic. These ads did not inform Heidi to have heightened vigilance for signs and symptoms of histoplasmosis while on Humira. Nor did they inform her of her additional increased risk by virtue of where she resided. If she had been told about this known, specific risk, she would have declined to take the drug.

22. *In toto*, the DTC advertising employed by Abbott failed to warn Heidi Cook about her true risks for developing disseminated histoplasmosis, misrepresented to her that Humira was a safer product than it actually was, and were misleading with respect to the promises about the

drug's appropriateness and safety for patients like her. This drug most certainly did not meet her expectations when she decided to take it. To her detriment and forever regret, Heidi relied on these ads in making a decision to start and continue taking Humira injections.

Safety Signals from the Clinical Trials

23. According to the 2003 Humira label, the efficacy of Humira for the treatment of RA was established in a scant four "pivotal" clinical trials. Only 2,070 patients were treated with the drug during the course of these trials. Three of these developed histoplasmosis. One died. On information and belief, Abbott, or its clinical investigators, made internal causality assessments that the histoplasmosis of one or more of these patients were "probably related" to their injections of Humira.

24. In subsequent clinical trials, at least one other patient developed histoplasmosis.

25. Although Abbott frequently tries to explain away these statistics by suggesting that the rate of infections was not substantially greater than the expected or background rate, in fact, no patients who were given placebos in the same trials developed histoplasmosis. Therefore, the "relative risk" was infinity. This should have been a major safety "signal" and should have prompted exceedingly stringent warnings, particularly in view of the fact that a competitor drug in the same class, *i.e.,* Remicade, already had a **BLACK BOX** warning about the risk of similar infections.

26. Abbott should have put a similar warning on its label and promotional materials for Humira at the time of the original launch. But its business analysis told it that differences in the labeling about side effects were very important for competitive purposes, and, although Remicade had a **BLACK BOX** warning about infections, Enbrel did not. Therefore, in order to compete more effectively against Enbrel/Remicade, Abbott delayed appropriate warnings about histoplasmosis. Indeed, even when the FDA exercised new legal authority on September 4, 2008 to "require" Black

Box histoplasmosis warnings within 30 days Abbott delayed the change until December 2008, and more importantly, delayed sending out any letters to doctors or patients alike about either the label change or the increased risk until May 2010. Regardless, this was too little, too late for Heidi Cook as she began taking Humira in April of 2008.

Notice from a Death, a Prestigious Medical Journal, and a Lawsuit

27. A young woman from Illinois died as a result of Humira-induced histoplasmosis. Her death was investigated and ultimately reported in a case study by the prestigious New England Journal of Medicine in 2009 and illustrates the kind of errors that were being made by physicians in diagnosing Humira-induced histoplasmosis, and the kind of reasonable pharmacovigilance that Abbott should have undertaken. Exhibit B, Frank, et.al., *Investigation of the Cause of Death in a Gene Therapy Trial,* 361:2 NEJM (July 9, 2009).

28. Like Heidi Cook, the young woman lived in a "hot zone," *i.e.,* the Ohio River Valley. Because she was also participating in a "gene therapy" clinical trial, when she died, her husband and her physicians thought that something about that trial must have killed her. However, the group of physicians who looked into the question concluded that her death was not caused by gene therapy at all. Rather, the cause of the patient's death "was primarily a result of disseminated histoplasmosis with subsequent bleeding complications and multi-organ failure. The apparent risk factor was the patient's systemic treatment with adalimumab." In other words, Humira killed her.

29. Long before Abbott received the FDA's September 4, 2008, mandate, her widower and children filed a wrongful death case against Abbott. *See Mohr v. Targeted Genetics, Inc.*, 690 F.Supp.2d 711 (C.D. Illinois 2007). This death and legal claim for same constitute "new safety information" within the purview of § 901 of the 2007 Amendments to the FDCA and "notice" to Abbott under West Virginia law. Internal Abbott documents evidence that Abbott was well aware

of this tragic case. In any event, this case should have prompted stringent warnings from this drug company.

More Red Flags from Adverse Event Data

30. As one can readily see, because clinical trials involve comparatively few patients, it is well recognized within the pharmaceutical industry that adverse event reports received from actual patients in the real world are a major, and important, source of safety information. The FDA's MedWatch program was set up to monitor this information.

31. Although anyone can file a report with the company or the FDA, the majority of such reports are filed by concerned physicians who suspect that a prescription drug is associated with their patient's adverse event.

32. Abbott, like other companies, collects data from all available sources about side effects that are reported to it and makes some attempt to determine the probable association or relationship between the drug and the reported side effect. Between the launch of the drug in early 2003 and the Fall of 2008 there were approximately 30 adverse event reports about histoplasmosis where Humira was the "suspect drug." In fact, histoplasmosis is the most frequently reported invasive fungal infection with all TNF inhibitors.

33. On information and belief, in one or more instances, Abbott's internal causality assessments for these cases reflected that one or more of them were, more likely than not, "associated with" or causally related to Humira. However, Abbott has not done the kind of thorough investigation and publication about such adverse events that a reasonable company should do. Nor did it act on them until forced by the FDA in September 2008.

34. These allegations are based on publically available information in the FDA adverse event database. Abbott maintains a more extensive database about Humira's reported adverse

events, but, to date, it has refused to produce that database, even under a court protective order and confidentiality designation. This is one of the ways that Abbott has concealed the full nature and extent of Humira's association with histoplasmosis and other serious opportunistic infections from the public and from Plaintiffs in this case. Plaintiffs reserve the right to amend these allegations with more particularized information, should the Abbott database ultimately be produced.

35. Because FDA regulations require the drug manufacturer to add a warning – in the warnings section of the label – whenever there is a "reasonable association" between the drug and a dangerous side effect, and further state that "a causal relationship need not be established" before a warning is required, this information from the adverse event database should have prompted Abbott to issue strong warnings about the risk of histoplasmosis. *See* 21 C.F.R. § 201.80(e).

36. Prior to Heidi's prescription for Humira, Abbott failed to appropriately and adequately warn about the risk of both Humira-induced histoplasmosis as well as the additional increase risk by virtue of where a patient may reside. It did so despite knowing differently. Heidi and her physicians were justified in relying upon the representations as to Humira's safety and appropriateness made to them by Abbott in their sales materials, marketing materials, and advertisements. As a result of this conduct, Heidi developed histoplasmosis and suffered.

FDA Finds Abbott's Psoriasis Ads Misleading

37. In January 2008, the FDA approved Humira for the treatment of psoriasis, the indication for which Heidi Cook was prescribed Humira. Abbott was anxious to market their drug for this new indication and devoted some portion of the $70 million dollars it spent in advertising in 2008 on this purpose.[8] Unfortunately, Abbott overstepped the truth in 2008 with its ads, the very

[8] Harrison and Star, a healthcare advertising and communications firm, was the recipient of Abbott's mega-advertising dollars at this time.

year Heidi was prescribed Humira, and the FDA caught them red-handed. Unfortunately, it was too late for Heidi.

38. Upon its launch in January 2008, Abbott "prominently" touted Humira as "[n]ow approved for moderate to severe chronic plaque psoriasis." Exhibit C. In December 2008, (eight months after the initial prescription at issue in this case) the FDA's Division of Drug Marketing, Advertising, and Communications ["DDMAC"] found this proclamation made to physicians and patients to be "misleading" because Abbott failed to further relay that the approved indication was not for *all* psoriasis patients but only a select group of them. *Id.* at 3. The FDA equally chastised Abbott for the misleading nature of its advertisement:

> "...because of the serious risks associated with this product, HUMIRA should only be administered to patients who will be closely monitored and *have regular follow-up visits with a physician*. Due to the drug's risk profile, the use of HUMIRA in plaque psoriasis needs to be very carefully considered, a message not conveyed in the ad."

Id. (Emphasis added). The FDA further found that the actual positioning of the safety information in the ad, "extremely small font," "misleading statement," and inaccurate pictorial representation left an "overwhelming impression" that inappropriately broadened the indication for Humira. *Id.* at 4. This "minimization" of "serious risk information," as determined by the FDA, "undermine[d] the communication of important risk information...and suggest[ed] that Humira is safer than has been demonstrated." *Id.* at 4. DDMAC directed Abbott to immediately cease the dissemination of these "violative" promotional materials.

39. Unfortunately, by the time the FDA discovered Abbott's misleading marketing efforts, the damage was done. Heidi Cook had already been prescribed Humira consistent with misleading ads but *inconsistent* with the corrected language later required by the FDA. Given these

facts, it is alleged doctor Michelle Endicott, M.D., Heidi's prescribing physician, actually saw and relied upon the misleading advertisement. This was to Heidi's obvious detriment.

Belated Warnings to the Patients and Doctors

40. On September 4, 2008, the FDA highlighted a number of cases of histoplasmosis and other invasive fungal infections not initially diagnosed in patients receiving TNF-alpha blockers. They told the manufacturers of those drugs that they needed to strengthen the warnings within 30 days of that news release "or provide a reason why they do not believe labeling changes are necessary." Exhibit D, FDA Press Release (9/4/08), incorporated herein by reference. This action by the FDA was in response to its review of 240 reports of histoplasmosis for patients taking TNF blockers. In at least 21 of those reports, histoplasmosis was initially not recognized by health care professionals, and treatment was delayed. Twelve of those patients died. *Id.* Importantly, FDA highlighted that the majority of the cases were occurring n the Ohio and Mississippi River Valleys.

41. In years past, the FDA did not have the legal authority to require warnings, revised labeling, and "mitigation strategies" of this nature. However, the 2007 amendments to the Food Drug and Cosmetic Act conferred the authority to require drug companies to implement Risk Evaluation and Mitigation Strategies ["REMS"]. Those statutory amendments became effective on March 25, 2008. *See* PL 110-85, 121 Stat 823 (September 27, 2007), amending 21 USC § 355. When Congress granted the FDA this authority, it reaffirmed that manufacturers remain responsible for the currency and content of their labels. However, Congress did make a significant change with regard to "who" must be warned.

42. Section 915 of the amending statute is entitled "Post Market Drug Safety Information for *Patients* and Providers." § 915, PL 110-85, 121 Stat 823 (emphasis added). It provides various

means for the FDA itself to communicate risks directly to patients. Section 901 empowers the FDA to implement "REMS" that require the drug company to warn patients directly.

43. Humira was one of the first drugs targeted by the FDA for a REMS program. In addition to ordering labeling changes and strengthening Patient Medication Guides, the September 4, 2008 release also directed Abbott to implement a REMS specifically focusing on the "risk" of histoplasmosis and other opportunistic infections in patients taking Humira and the ways to "mitigate" that risk, *inter alia*, by alerting patients directly of the risk. As the FDA said, "Patients taking TNF blockers should *be aware* that they are more susceptible to serious fungal infections. . . . "; especially those patients in endemic areas like the Ohio and Mississippi River Valleys.

44. It appears that the physicians who were treating Heidi Cook were not actually aware of the risk of Humira-induced histoplasmosis. Nor were they aware of Heidi's increased risk by virtue of where she resided, in the Ohio River Valley. But whether the doctors knew, or did not know, Heidi Cook was certainly not "aware" of this risk. She was never made aware because Abbott failed to adhere to the FDA directive to warn either the physicians or her directly.

45. Mrs. Cook should have also been made "aware" before she received her first injection of Humira on April 17, 2008, that she was at high risk for a fungal infection. However, IF Abbott had acted promptly and responsibly she would have been. But Abbott did not act promptly or proactively.

46. Even though the FDA's September 4, 2008, directive required warnings within "30 days," Abbott drug its heels until May 17, 2010, before it sent out its "Dear Healthcare Professional" letter, attached as Exhibit E and incorporated herein by reference. The letter was designed to "bring home" the warning to prescribing physicians. To catch their eye, it began with the following graphic (reproduced below in scale and red ink, as was the original):

47. Abbott's "Dear Doctor" letter begins with an acknowledgment that it concerns "an important expanded safety update about HUMIRA (adalimumab) and the risk of developing unrecognized histoplasmosis and other invasive fungal infections." The lack of a prompt diagnosis "has resulted in delays in appropriate antifungal treatment, *sometimes resulting in death*." *Id.* (Emphasis added). It then cautions physicians that "[h]istoplasmosis and other invasive fungal infections can go *unrecognized* unless a *high index of suspicion* is maintained."

48. No such warning was ever sent to Heidi Cook or her doctors prior to April of 2008, and had it been she would have not taken Humira.

Heidi Cook and Humira

49. Heidi Cook and her husband Steven lived in West Virginia most of their lives but moved to Kentucky in July of 2010. They have three young children, ages 3, 6, and 9.

50. After the birth of her second child in August of 2006, Heidi began to experience symptoms consistent with psoriasis . She was treated with topical medications and steroids until April of 2008 when the decision was made to switch Heidi to Humira by her West Virginia dermatologist, Michelle Endicott, M.D.

51. At no time was Heidi warned about any potential risk of serious fungal infections such as histoplasmosis when she was first prescribed Humira. Nor was she warned that Humira put her at increased risk of hospitalization or death from histoplasmosis not only because she was taking the drug, but also because she resided in the "hot zone" that is the Ohio River Valley.

52. If Abbott had appropriately warned Heidi or her doctors, she could have made an informed decision as to whether or not she would ever have started taking Humira. She would also have been better able to assist doctors with her care and potentially saved herself from additional suffering. This information was never properly or adequately provided to Heidi Cook or her physicians.

53. From approximately April 2008 to August 2008 Heidi received biweekly Humira injections until she became pregnant and stopped the medication. Due to a flare of her psoriasis, on December 14, 2009, a new dermatologist, Amy Vaughn, M.D., put her back on Humira. Except for a brief period of time in March 2010, Heidi Cool continued bi-weekly injections until July 26, 2011, when Dr. Vaughn modified Humira injections to monthly. From July 26, 2011 through October 7, 2011, Mrs. Cook received monthly Humira injections until her last dose on October 7, 2011.

54. On October 7, 2011, Mrs. Cook presented to the office of Joel Knight, M.D., primary care physician, with symptoms of an increase in myalgia and arthralgia. At the time of this visit, Dr. Knight administered an influenza vaccine. By October 10, 2011, Dr. Knight noted that Mrs. Cook complained of a fever of 102, in addition to myalgia. She was advised to treat symptomatically and report back if her symptoms did not resolve. On October 11, 2011, Mrs. Cook had developed fatigue, malaise and loss of appetite in addition to her fever and myalgia. Supportive care was recommended for viral illness.

55. By October 12, 2011, due to persistent fever and myalgia, malaise and fatigue, Mrs. Cook contacted Dr. Vaughn and was advised to hold her Humira. Labs were obtained and showed elevated liver function studies. Her CBC showed an elevated lymphocyte count suggesting an evolving infection. Mono screen was obtained in Dr. Vaughn's office and noted to have been positive. Heidi continued to be treated for viral illness.

56. By October 21, 2011, Mrs. Cook returned to Dr. Knight's office with persistent daily fever to 101, extreme fatigue, shortness of breath with activity, and nonproductive cough. At this time, urine histoplasma antigen was obtained and reported negative. Chest x-ray was obtained and was reported with "bilateral infiltrates consistent with an infectious process." Dr. Knight prescribed Zithromax and ProAir, a bronchodilator.

57. Through November 3, 2011, Mrs. Cook's symptoms remained persistent. She was admitted through the emergency room at Georgetown Community Hospital on November 3, 2011 where she was diagnosed with severe bilateral pneumonia.

58. Records from Georgetown Community Hospital on November 3, 2011 show that Mrs. Cook had developed worsening respiratory failure. Serial chest x-rays were performed and showed worsening bilateral pneumonia. Due to the need for pulmonary and infectious disease management, Mrs. Cook was transferred to the University of Kentucky Medical Center on November 5, 2011.

59. Following transfer to the University of Kentucky Medical Center on November 5, 2011, Mrs. Cook was placed on respiratory isolation. Lab work showed persistent elevation of liver function tests. Immune globulin panel showed elevation as well, indicative of active infection. Internist, Charles G. Sargent, M.D., attending physician noted that the elevated liver function tests could be secondary to adalimumab (Humira).

60. Chest CT scan on November 5, 2011 showed military pattern and presence of an active interstitial infection. Pulmonary Medicine consult was obtained as well as Infectious Disease consultation with Richard Greenberg, M.D. Dr. Greenberg suspected a fungal infection, "probably histoplasmosis," and ordered a battery of tests including urine histoplasma antigen which was reported as positive on November 5, 2011. Mrs. Cook was quickly started on Amphotericin.

61. By November 6, 2011, chest x-ray showed progression of the bilateral interstitial infiltrates. Lab work began to show evidence of acute renal failure. A dialysis catheter was placed, but prior to starting dialysis, the kidney function tests began to improve. Prior to discharge, she was placed on Itraconazole 200 mg twice daily to be followed by the Infectious Disease Service as an outpatient.

62. Following discharge from University of Kentucky Hospital Medical Center, Mrs. Cook was followed by Infectious Disease Specialist, Michael Young, M.D. who recommended continuation of Itraconazole 200 mg twice daily, this was continued until May 2012 with side effects of hair loss.

63. Mrs. Cook has been advised by Dr. Young that she will continue to be at risk for reactivation of her Histoplasmosis infection for the remainder of her life despite the fact that it had been treated with Itraconazole. Dr. Young has also advised her to never take another biologic agent due to her history of histoplasmosis infection.

64. As a result of the severe bilateral pneumonia due to histoplasmosis, Heidi has reduced stamina and endurance. She has three young children, ages 3,6, and 9 years old, and this presents significant challenges for her. Further, she fatigues easily and it would be difficult for her to return to her previous job as a commercial banking lender.

65. These consequences are all a result of Abbott's failure to timely and adequately warn patients and doctors of the true risk of histoplasmosis in patients taking Humira, particularly those who lived in high-risk areas like Heidi Cook.

Causes of Action

The foregoing facts give rise to legally cognizable claims against Abbott under the common and/or statutory law of West Virginia as follows:

66. FIRST - STRICT LIABILITY. Plaintiff asserts a cause of action for strict products liability under the law of West Virginia. Humira is "unreasonably dangerous" and/or "defective" under West Virginia law. Additional product liability theories include design defect, failure to warn, and misrepresentation.

67. SECOND - NEGLIGENCE. Defendants were negligent in the design and testing of the drug Humira, in the marketing and promotion of the drug, and in the collection and analysis of adverse event data, and said negligence was a proximate or legal cause of Plaintiff's disseminated histoplasmosis. Therefore, Defendants are liable for negligence under the common law of West Virginia. As a direct and legal result of the negligence of Defendants and/or its agent(s), Plaintiff has sustained serious and permanent injuries including, but not limited to the reduced stamina and endurance; fatigues easily; mental anguish; loss of some capacity or ability to enjoy life as fully as before; expense of hospitalization; cost of medical, nursing care, and rehabilitation; loss of earnings and loss of the ability to earn money in the future. Plaintiff's injuries and losses are continuing in nature as she may never regain her previous energy level and will have to be routinely evaluated for the rest of her life to determine if there has been a reoccurrence of histoplasmosis.

68. THIRD - WARRANTY. It was entirely foreseeable and known to Defendants that individuals like Heidi Cook who reside in histoplasmosis "hot zones" would be prescribed their

drug. Because Defendants failed to adequately package, label, or otherwise warn both patients and doctors about the increased risks of histoplasmosis, as well as, the increased risk because of where they resided, Defendants breached West Virginia's implied warranty of merchantability.[9]

69. Further, Plaintiff relied, not only on the recommendations of her doctor, but also on the reputation and representations that Defendants made in their advertisements that she saw prior to taking, and during her use of the drug. These ads portrayed happy people that affirmed the drug was safe and effective. Yet, unbeknownst to her, the drug was not appropriate for all people and greatly increased her risk of developing histoplasmosis. Because Defendant Abbott has breached its express warranty obligations under West Virginia law, it is further liable to Plaintiff for her injuries.

Damages and Remedies

70. Plaintiffs sues to recover all elements of compensable damages under West Virginia law, to include compensation for her increased risk of further histoplasmosis in the future and the medical monitoring costs associated with such. *Bower v. Westinghouse Elec. Corp.*, 206 W. Va. 133, 140, 522 S.E.2d 424, 431 (1999)("We therefore align this jurisdiction with those that have considered the issue, and conclude that a cause of action exists under West Virginia law for the recovery of medical monitoring costs, where it can be proven that such expenses are necessary and reasonably certain to be incurred as a proximate result of a defendant's tortious conduct."). Plaintiff Steven Cook sues for loss of his share of family earnings and for loss of consortium. W. Va. Code Ann. § 48-29-302 (West). Additionally, she seeks appropriate prejudgment interest thereon, as provided by law.

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[9] *See Hines v. Wyeth*, CIV.A. 2:04-0690, 2011 WL 1990496 at 2-3 (S.D. W.Va. May 23, 2011) and Section 46–2–314 of the West Virginia Code.

71. If the evidence at trial demonstrates Abbott engaged in willful and/or wanton conduct that evidences an utter indifference or conscious disregard for the safety of patients like Plaintiff, then the Jury may, in its discretion, award punitive or exemplary damages, and should, in fact, do so.

Jury Demand

72. Plaintiffs invoke their constitutional right to trial by jury.

Prayer for Relief

WHEREFORE, Plaintiffs Heidi and Steven Cook pray that Defendants Abbott Laboratories and AbbVie, Inc., be cited to appear and answer herein, and that upon the final trial of this case, a Final Judgment be entered by this Court in Plaintiffs' favor against Defendants for such compensatory and punitive damages as are appropriate, plus interest and costs of litigation, and awarding such other and further relief as is just and proper.

Respectfully submitted,

PIERSON LEGAL SERVICES

/s/ James M. Pierson
James M. Pierson
W. Virginia Bar #2907
5300 MacCorkle Avenue SE
Charleston, WV 25304
Telephone: 304-925-2400
Facsimile: 304-925-2603
Email: jpierson@piersonlegal.com
Counsel for Plaintiffs

and

Arnold Anderson (Andy) Vickery
Texas Bar No. 20571800
Jim M. Perdue, Jr.
Texas Bar No. 00788180
Fred H. Shepherd
Texas Bar No. 24033056
Brian B. Winegar
Texas Bar No. 24081218
PERDUE KIDD & VICKERY
510 Bering Dr., Suite 550
Houston, TX 77057-1469
Telephone: 713-520-2500
Facsimile: 713-520-2525
Email: andy@justiceseekers.com
Email: jperduejr@justiceseekers.com
Email: fred@justiceseekers.com
Email: bwinegar@justiceseekers.com
Lead Counsel for Plaintiffs
[Admittance *Pro Hac Vice* to be sought]